LUMEX Analytical Equipment

REAL-TIME MICROCHIP PCR ANALYZER
AriaDNA®

MICROCHIP RT-PCR COVID-19 DETECTION SYSTEM

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) also known as 2019 novel coronavirus (2019-nCoV). Since the World Health Organization (WHO) declared the coronavirus outbreak pandemic, there is a dire need of its detection accurately, rapidly, and cost effectively. The standard method of testing is real-time reverse transcription polymerase chain reaction (RT-PCR) performed on respiratory samples such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate.

The US Center for Disease Control and Prevention (CDC) has designed RT-PCR assays and published a protocol for detection of SARS-CoV-2. Integrated DNA Technologies, Inc. (IDT) provides 2019-nCoV CDC primers-probes for the CDC assays.

To achieve rapidity, cost-effectiveness, minimization of reagent consumption, decrease of human errors, Lumex Instruments Canada has developed a **Microchip RT-PCR COVID-19 detection system** that use a pre-loaded microchip kit with the CDC recommended primers & probes lyophilized in the microchip for testing of the SARS-CoV-2, as research use only (RUO) application. The N1 and N2 primer-probes target regions within the SARS-CoV-2 nucleocapsid gene (N), and HsRPP30 targets RNase P gene present in the human genome.

FEATURES and BENEFITS:

- Current real-time PCR assays and PCR instruments consume large volume of reagents (20 µl reaction). The test can be costly and suffer from potential bottleneck of PCR reagent supply in the event of disease outbreaks.
- Main advantages of the Microchip RT-PCR COVID-19 detection system are low reagent consumption (1.2 µl reaction), fast analysis, shipment under ambient conditions and convenient process of PCR analysis.
- The Microchip RT-PCR COVID-19 detection system would provide sensitive, specific, and fast detection of SARS-CoV-2 viral RNA with low reagent consumption.
- Ease of use with lyophilized PCR reagents in the microchips will significantly improve reliability of analysis in fast-responder settings by reducing operator-associated errors.
- The Microchip RT-PCR COVID-19 detection system – compact and low-energy requiring – is ready to be deployed as point-of-analysis network.
- Early detection of pathogens will minimize economic loss due to outbreaks. This technology would help maintain public health and improve effectiveness of quarantine measures. Microchip kits can be designed for specific pathogen applications in future outbreaks.

USER-FRIENDLY SOFTWARE

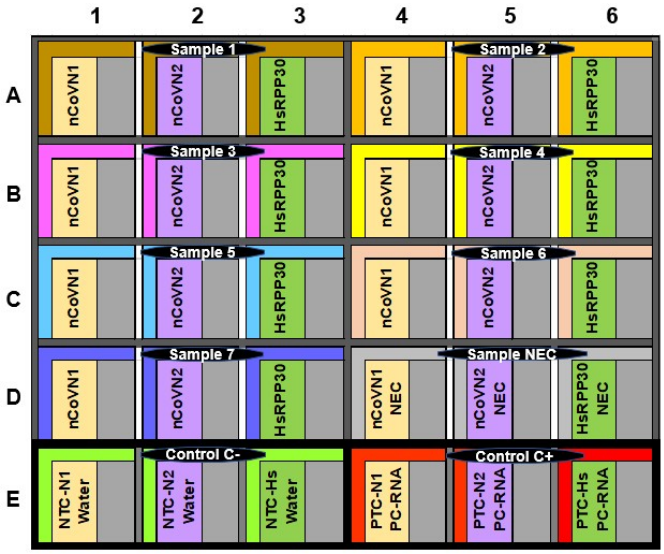
Designed to acquire real-time PCR data and allows simplified operation steps. It offers auto-interpretation of results, allows manual analysis of data, and prints report in compliance with 21 CFR part 11 requirements.

FLUORESCENCE DETECTION

Two detection channels of AriaDNA analyzer report the following panels of targets:

Channel 1 (FAM)	1. SARS-CoV-2 N-gene: N1, 2. SARS-CoV-2 N-gene: N2, and 3. Human RNase P gene HsRPP30 (Internal Control)
Channel 2 (Cy5)	Not employed by the kit

LAYOUT OF MICROCHIP



Test panel:

- nCoVN1 (SARS-CoV-2 N1)
- nCoVN2 (SARS-CoV-2 N2)
- HsRPP30 (Internal Control)

Controls:

- NEC (Negative extraction control)
  - Run with NEC sample
- PTC (Positive template control)
  - Run with SARS-CoV-2 RNA
- NTC (Negative template control)
  - Run with nuclease free water

Number of samples per chip:
7 patient samples can be analyzed.

ANALYSIS FLOW CHART

1. **Pre-loaded microchips:** Require a separate purchase of the following kits to run the test. List of the kits recommended by CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, For Emergency Use Only, Instruction for Use: CDC-006-00019, Revision: 03, can be seen at the link https://www.fda.gov/media/134922/download:
   a. **RNA extraction kit:** To extract RNA from test samples, the list of the kits is presented at page # 8 of the above-said document.
   b. **Master Mix solution**: The list of master mixes such as TaqPath™ 1-Step RT-qPCR Master Mix, CG or Quantabio qScriptTM XLT One-Step RT-qPCR ToughMix or UltraPlex 1-Step ToughMix, or Promega GoTa Probe 1-Step RT-qPCR System is present at page # 25 of the above-said document. Consumption of the Master Mix per sample will be reduced 10 times compared with the recommended volumes for conventional PCR.
2. **Empty microchips**: require a separate purchase of recommended primers & probes https://www.idtdna.com/pages/landing/coronavirus-research-reagents in addition to the above-said RNA Extraction Kit and Master Mix solution. Consumption of the PCR reagents per sample will be decreased 5 times compared with the recommended volumes for conventional PCR.
3. **Test procedure**: Mix the RNA extracted from the sample with required reagents and then dispense this mixture into microchip by following instruction manual supplied with the microchips. Then insert the microchip into AriaDNA analyzer and run the analysis with a pre-set protocol on a computer.
4. **Estimated microchip consumption rate:** 8 microchips per day per instrument (8h work shift), i.e. 40 microchips a week per single AriaDNA instrument can be consumed. A reasonable amount to order per 1 instrument per 1 month is 200-250 microchips (8-10 boxes). Larger quantities of microchips can be blanket ordered.

RESULTS

- Obtain real-time RT-PCR results and print report in 50 minutes.
- Detection limit equals 9×10^3 copies in 1 mL of the sample.

For research use only (RUO). Positive results should not be used as the sole basis for treatment or other patient management decisions. Positive results are indicative of active infection with 2019-nCoV provided other clinical observations, patient history and epidemiological information are in line with the results. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.